

Technical Requirements-ER checklist

Product:	GenBody COVID-19 Ag
Date:	2020-06-09

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0. Revision history

Revision History		
Rev.O	2020. 06. 02	Release of the essential requirement checklists for the GenBody COVID-19 Ag
Rev 0.1	2020. 06. 09	Updated information

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A. GENERAL REQUIREMENTS (Application: *A-Applicable, *N/A-Not Applicable)

Essential Requirement	A N/A	Standard	Manufactures and Compliance	Locations
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	A	EN ISO18113-2:2011 EN ISO 14971:2012	User's Guide Risk management report	Introduction, General Precautions TCF chapter 3_risk management
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	EN 13641:2002 EN ISO 14971:2012	Risk management report	TCF chapter 3_risk management TCF chapter 5_Specification of materials
3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.	A	EN ISO17511:2003 EN 13612:2002 EN ISO 23640:2015	Performance evaluation report Stability test report User's Guide	TCF chapter 7_Performance evaluation TCF chapter 8_Stability studies TCF Chapter 5_Specification

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				of materials
<p>4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.</p>	A	EN ISO18113-2:2011 EN 13612:2002 EN ISO 23640:2015	Stability test report User's Guide	TCF chapter 8_Stability studies
<p>5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.</p>	A	EN ISO18113-2:2011 EN ISO 15223-1:2016 EN ISO 14971:2012	User's Guide Shipping simulation test report Risk management report	TCF chapter 8_Stability studies TCF chapter 3_Risk management

B. DESIGN AND MANUFACTURING REQUIREMENTS

Essential Requirement	A N/A	Standard	Manufactures and Compliance	Locations
1. Chemical and physical properties 1.1 The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in section A on the 'General requirements'. Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	A	EN 13612:2002 EN ISO 14971:2012	Performance evaluation report Manufacturing document User's Guide Risk management report	TCF chapter 7_Performance evaluation, 8_Stability studies, 9_manufacturing Specification Chapter 3_Risk management

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<p>1.2 The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.</p>	A	<p>EN ISO18113-2:2011</p> <p>EN ISO 14971:2012</p> <p>EN ISO 23640:2015</p> <p>EN 13975: 2003</p>	<p>Shipping simulation test report</p> <p>Packaging document</p> <p>User's Guide</p> <p>Risk management report</p>	<p>TCF chapter 9_Stability studies</p> <p>TCF chapter 4_label</p> <p>TCF chapter 3_Risk management</p>
<p>2. Infection and microbial contamination</p> <p>2.1 The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.</p>	N/A	N/A: This kit has not any contamination sources.		
<p>2.2 Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.</p>	N/A	N/A: This kit has not any contamination sources.		
<p>2.3 Devices labeled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.</p>	N/A	N/A: This kit is not necessary to be sterile.		

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2.4 Devices labeled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.	N/A			
2.5 Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	N/A	N/A: This kit has not any contamination sources.		
2.6 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	N/A	N/A: This kit is not necessary to be sterile.		
2.7 Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	A	EN 13641:2002 EN ISO 14971:2012	Shipping simulation test report Packaging document User's Guide Risk management report	TCF chapter 9_Stability studies TCF chapter 4_label TCF chapter 3_Risk management

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<p>3. Manufacturing and environmental properties</p> <p>3.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/or in the User's Guide.</p>	<p>A</p>	<p>EN ISO 14971:2012</p> <p>EN ISO18113-2:2011</p>	<p>User's Guide</p> <p>Performance evaluation report</p>	<p>IFU, Intended use, work flow, related instruments</p> <p>TCF chapter 7_Performance evaluation</p>
<p>3.2 Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use.</p>	<p>A</p>	<p>EN ISO 14971:2012</p>	<p>User's Guide</p> <p>Specimen storage stability</p> <p>Risk management report</p>	<p>IFU, Specimen</p> <p>TCF chapter 8_Stability studies</p> <p>TCF chapter 3_Risk management</p>
<p>3.3 Devices must be designed and manufactured in such a way as to remove or reduce as far as possible:</p> <ul style="list-style-type: none"> - the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features), - risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device. <p>Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.</p>	<p>N/A</p>	<p>N/A: This kit is not an In-Vitro Diagnostic electrical instrument, but an IVD reagent.</p>		

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<p>3.4 Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.</p>	<p>N/A</p>	<p>N/A: This kit has not any fire, explosion sources.</p>		
<p>3.5 Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.</p>	<p>A</p>	<p>EN ISO18113-2:2011 EN ISO 14971:2012</p>	<p>User's Guide Performance evaluation control procedure Risk management report</p>	<p>IFU, Safety warnings and precautions, preparation TCF chapter 5_spefication of materials TCF chapter 3_Risk management</p>
<p>3.6 The measuring, monitoring or display scale (including color change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.</p>	<p>N/A</p>	<p>N/A: This kit is an IVD reagent. This step is not relevant to an IVD reagent kit.</p>		
<p>4. Devices which are instruments or apparatus with a measuring function 4.1 Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.</p>	<p>N/A</p>	<p>N/A: This kit is an IVD reagent kit, not an instrument or an apparatus, that has a primary analytical measuring function.</p>		

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<p>4.2 When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement (1).</p>	<p>N/A</p>	<p>N/A: This kit is complied with Directive 98/79/EC.</p>
<p>5. Protection against radiation 5.1 Devices shall be designed; manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimized.</p>	<p>N/A</p>	<p>N/A: This kit is not exposed visible and invisible radiation.</p>
<p>5.2 When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: - designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted, - fitted with visual displays and/or audible warnings of such emissions.</p>	<p>N/A</p>	<p>N/A: This kit is not exposed visible and invisible radiation.</p>
<p>5.3 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.</p>	<p>N/A</p>	<p>N/A: This kit is not exposed visible and invisible radiation.</p>
<p>6. Requirements for medical devices connected to or equipped with an energy source 6.1 Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.</p>	<p>N/A</p>	<p>N/A: This kit is not an In-Vitro Diagnostic electrical instrument, but an IVD reagent.</p>
<p>6.2 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.</p>	<p>N/A</p>	

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<p>6.3 Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.</p>	<p>N/A</p>	
<p>6.4 Protection against mechanical and thermal risks</p> <p>6.4.1 Devices must be designed and manufactured in such a way as to protect the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.</p> <p>Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.</p> <p>Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.</p>	<p>N/A</p>	
<p>6.4.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.</p>	<p>N/A</p>	
<p>6.4.3 Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.</p>	<p>N/A</p>	
<p>6.4.4 Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimize all possible risks.</p>	<p>N/A</p>	

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<p>6.4.5 Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.</p>	<p>N/A</p>	
<p>7. Requirements for device for self-testing</p> <p>7.1 Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.</p>	<p>N/A</p>	<p>N/A: This kit is not designed for self-testing, but for profession.</p>
<p>7.2 Devices for self-testing must be designed and manufactured in such a way as to:</p> <ul style="list-style-type: none"> - ensure that the device is easy to use by the intended lay user at all stages of the procedure, and - reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results. 	<p>N/A</p>	
<p>7.3 Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.</p>	<p>N/A</p>	

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<p>8. Information supplied by the manufacturer</p> <p>8.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and in the User's Guide As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labeling of each unit is not practicable, the information must be set out on the packaging and/or in the User's Guide supplied with one or more devices. The User's Guide must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such User's Guide are needed for a device if it can be used properly and safely without them.</p>	<p>A</p>	<p>EN ISO18113-2:2011 EN ISO 15223-1:2016 EN ISO 23640:2015 EN 13612:2002</p>	<p>Shipping simulation test report Packaging document User's Guide Risk management report</p>	<p>TCF chapter 8_Stability studies TCF chapter 4_label IFU, General precautions, symbols TCF chapter 3_Risk management</p>
<p>8.2 Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and color used must be described in the documentation supplied with the device.</p>	<p>A</p>	<p>EN ISO18113-2:2011 EN ISO 15223-1:2016</p>	<p>User's guide Labeling</p>	<p>IFU Manufacturer information, symbol TCF chapter 4_label</p>

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<p>8.3 In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labeling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the User's Guide.</p> <p>The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the User's Guide.</p>	<p>N/A</p>	<p>N/A: This kit is complied with Directive 98/79/EC.</p>		
<p>8.4 The label must bear the following particulars which may take the form of symbols as appropriate:</p> <p>(a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the User's Guide shall contain in addition the name and address of the authorized representative of the manufacturer;</p> <p>(b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;</p> <p>(c) where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;</p> <p>(d) the batch code, preceded by the word 'LOT', or the serial number;</p> <p>(e) if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;</p> <p>(f) in case of devices for performance evaluation, the words 'for performance evaluation only';</p> <p>(g) where appropriate, a statement indicating the in vitro use of the device;</p>	<p>A</p> <p>A</p> <p>N/A</p> <p>A</p> <p>A</p> <p>N/A</p> <p>A</p>	<p>EN ISO18113-2:2011</p> <p>EN ISO 15223-1:2016</p>	<p>User's Guide</p> <p>Labeling</p> <p>(c) N/A: This kit is not necessary to be sterile.</p> <p>(f) This kit is not only for performance evaluation, but for diagnosis.</p>	<p>IFU</p> <p>Manufacturer information, symbol</p> <p>TCF chapter 4_label</p>
<p>(h) any particular storage and/or handling conditions;</p>	<p>A</p>			<p>IFU,</p>

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(i) where applicable, any particular operating instructions;	A	EN ISO18113-2:2011 EN ISO 15223-1:2016	User's Guide	Manufacturer information, symbol TCF chapter 4_label
(j) appropriate warnings and/or precautions to take;	A		Labeling	
(k) if the device is intended for self-testing, that fact must be clearly stated.	N/A		(k) N/A: This kit is not designed for self-testing, but for professionals.	
8.5 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the User's Guide and, if appropriate, on the label.	A	EN ISO18113-2:2011 EN ISO 15223-1:2016	User's Guide Risk management report	IFU TCF chapter 3_Risk management 3.7 &3.8
8.6 Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	A	EN ISO18113-2:2011 EN ISO 15223-1:2016	User's Guide Labeling Risk management report	IFU, Symbol TCF chapter 4_label TCF chapter 3_Risk management
8.7 Where appropriate, the User's Guide must contain the following particulars: (a) the details referred to in section 8.4 with the exception of points (d) and (e); (b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	A A	EN ISO18113-2:2011 EN 13612:2002 EN ISO 23640:2015	User's Guide Raw material QC document	IFU Storage and expiration date,

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<p>(c) the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;</p> <p>(d) the performances referred to in section 3 of part A;</p> <p>(e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;</p> <p>(f) the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;</p> <p>(g) a detailed description of the procedure to be followed in using the device;</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>		<p>Performance evaluation report</p> <p>Specification of material</p>	<p>specimen</p> <p>TCF chapter 7_Performance evaluation</p> <p>TCF chap 1_Product description, 5_Specification of materials</p>
<p>(h) the measurement procedure to be followed with the device including as appropriate:</p> <ul style="list-style-type: none"> - the principle of the method, - the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user, - the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.), - the indication whether any particular training is required; <p>(i) the mathematical approach upon which the calculation of the analytical result is made;</p> <p>(j) measures to be taken in the event of changes in the analytical performance of the device;</p>	<p>A</p> <p>A</p> <p>N/A</p>	<p>EN ISO18113-2:2011</p> <p>EN 13612:2002</p> <p>EN ISO 23640:2015</p>	<p>User's Guide</p> <p>Performance evaluation report</p> <p>(j) There are no changes after diagnosis.</p>	<p>IFU, Introduction, features and principle of the test, contents and related instruments, storage and expiration date, protocol, specification</p> <p>TCF chapter 7_Performance evaluation, 8_Stability studies</p>

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<p>(k) information appropriate to users on: - internal quality control including specific validation procedures, - the traceability of the calibration of the device;</p> <p>(l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;</p> <p>(m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;</p> <p>(n) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;</p> <p>(o) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);</p> <p>(p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilization or decontamination;</p>	<p>A</p> <p>A</p> <p>A</p> <p>N/A</p> <p>N/A</p> <p>A</p>		<p>(n) N/A: This kit is not necessary for maintenance and calibration.</p> <p>(o) N/A: This kit is not necessary for pre-handling.</p>	
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<p>(q) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilization or decontamination, and any restriction on the number of reuses;</p>	<p>N/A</p>	<p>N/A: This kit has not to be reused.</p>
<p>(r) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;</p>	<p>A</p>	<p>A: Follow the User's Guide; Storage and Expiration date</p>
<p>(s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;</p>	<p>A</p>	<p>A: This kit uses Antibody and etc.</p>
<p>(t) specifications for devices for self-testing: - the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result, - specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device, - the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner, - the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;</p>	<p>N/A</p>	<p>EN ISO18113-2:2011</p>
<p>(u) date of issue or latest revision of the User's Guide.</p>	<p>A</p>	<p>User's Guide (IFU)</p>